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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/690,019	10/20/2003	Jeremy Nathans	JHU1380-2	5064

7590 01/14/2008

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EXAMINER	
DUFFY, PATRICIA ANN	
ART UNIT	**PAPER NUMBER**
1645	

MAIL DATE	DELIVERY MODE
01/14/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/690,019	NATHANS ET AL.	
	Examiner	Art Unit	
	Patricia A. Duffy	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 October 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *19-37 and 40-47* is/are pending in the application.

4a) Of the above claim(s) *21-37* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *19-37 and 40-47* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *2007*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

RESPONSE TO AMENDMENT

The amendment filed 10-12-07 has been entered into the record. Claims 1-18 and 38-39 have been cancelled. Claims 19-37 and 40-47 are pending. Claims 19, 20 and 40-47 are under examination.

The text of Title 35 of the U.S. Code not reiterated herein can be found in the previous office action.

Election/Restrictions

Newly submitted claims 19 as directed to SEQ ID NO:11 is directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: SEQ ID NO:11 is a species of the generic claim. The species is independent and distinct from SEQ ID NO:4 because they fail to share the same structure and the generic claim was anticipated by the art. As such, SEQ ID NO:11 is withdrawn from consideration as a distinct species.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims as drawn to SEQ ID NO:11 is withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Rejections Withdrawn

The rejection of claims 19 and 38-40 under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter is withdrawn based on Applicants amendments to the claims.

The rejection of claims 19, 20 and 38-40 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is withdrawn based on Applicants amendments to the claims.

The rejection of claims 19, 20 and 38-40 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is withdrawn based on Applicants amendments to the claims..

The rejection of claims 19 and 38-40 under 35 U.S.C. 102(b) as being anticipated by Patry et al (FEBS Letters, 349:23-28, 1994) is withdrawn based on Applicants amendments to the claims.

The rejection of claims 19, 20, 40, 41, 42 under 35 U.S.C. 102(e) as being clearly anticipated by Nathans et al (5,872,226, with priority to May 12, 1995) is withdrawn in favor of the rejection over Greene et al.

Rejections Maintained

Claims 19, 20 and 40-45 stand rejected under 35 U.S.C. 102(e) as being clearly anticipated by Greene et al (US Patent No. 6,482,408, with priority to June 5, 1995) is maintained for reasons made of record.

Applicants' arguments have been considered but are not persuasive. Applicant argues that since Greene et al does not teach SEQ ID NO:4 or 11, that the reference does not inherently anticipate the instantly claimed invention because the antibodies of the prior art may bind regions that are different. This is not persuasive, the claims are not limited to regions of difference. This is also not persuasive because Greene et al

claims antibodies or portions thereof that bind SEQ ID NO:2 or fragments consisting of 30 or 50 contiguous amino acids thereof or fragments having cellular growth activity. Greene et al contemplates monoclonal antibodies, polyclonal antibodies, chimeric antibodies, humanized antibodies, single chain antibodies and Fab fragments and compositions comprising such. Given that the polypeptide of the prior art has at least 117 consecutive residues that are identical with SEQ ID NO:4 (as shown below), the claimed antibodies of the prior art would inherently bind SEQ ID NO:4 of FHF-4 because the claimed sequence has at least 30-50 contiguous amino acids in common with SEQ ID NO:2 of the prior art. As such, the claimed antibodies to the identical contiguous regions of the two proteins would necessarily bind the other protein, not withstanding the regions of difference. Regions of similarity are known to provide for cross-reactivity of an antibody. It was well established in the art at the time the invention was made that antibodies raised to one polypeptide would also specifically bind other polypeptides sharing the epitope recognized by the antibody. For example, Bost et al. (Immunol. Invest. 1988; 17:577-586) teach that an antibody specifically bound an epitope shared by two different polypeptides, but did not bind irrelevant peptides not sharing this epitope. The epitope was determined to be a homologous sequence in the two proteins in which 4 of 6 residues were identical (see entire document, but especially the Abstract, Discussion, and "Results", page 579). Similarly, Bendayan (J. Histochem. Cytochem. 1995; 43:881-886) characterized the specific reactivity of a monoclonal antibody produced to human proinsulin and showed that although the antibody was highly specific, it bound to not only human proinsulin, but to proinsulin from other species (see entire document).

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RESULT 27
JS-09-425-021-2
: Sequence 2, Application US/09425021
: Patent No. 6482408
: GENERAL INFORMATION:
:  APPLICANT: Greene, John M.
:  APPLICANT: Rosen, Craig A.
:  TITLE OF INVENTION: Fibroblast Growth Factor 15
:  FILE REFERENCE: PF203D1
:  CURRENT APPLICATION NUMBER: US/09/425,021
:  CURRENT FILING DATE: 1999-10-25
:  EARLIER APPLICATION NUMBER: 09/103,079
:  EARLIER FILING DATE: 1998-06-23
:  NUMBER OF SEQ ID NOS: 32
:  SOFTWARE: PatentIn Ver. 2.0
: SEQ ID NO 2
:   LENGTH: 252
:   TYPE: PRT
:   ORGANISM: Homo sapiens
JS-09-425-021-2

  Query Match             74.0%;  Score 953.5;  DB 2;  Length 252;
  Best Local Similarity   80.2%;  Pred. No. 5.8e-98;
  Matches  190;  Conservative    4;  Mismatches   14;  Indels   29;  Gaps    3;

Qy          39 LCN---------GNLVDIFSKVRIF------------------GLKKRRLRRQDPQLKG 70
               |||           |:| ||   ::                  ||| :    ||||||
Db          17 LCNHKDLFFLRVSKLLDCFSPKSMWFLWNIFSKGTHMLQCLCGKSLKKNK-NPTDPQLKG 75

Qy          71 IVTRLYCRQGYYLQMHPDGALDGTKDDSTNSTLFNLIPVGLRVVAIQGVKTGLYIAMNGE 130
               |||||||||||||||||||||||| |||||||||||||||||||||||||||| ||||
Db          76 IVTRLYCRQGYYLQMHPDGALDGTKGDSTNSTLFNLIPVGLRVVAIQGVKTGLYITMNGE 135

Qy         131 GYLYPSELFTPECKFKESVFENYYVIYSSMLYRQQESGRAWFLGLNKEGQAMKGNRVKKI 190
               ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db         136 GYLYPSELFTPECKFKESVFENYYVIYSSMLYRQQESGRAWFLGLNKEGQAMKGNRVKKT 195

Qy         191 KPAAHFLPKPLEVAMYREPSLHDVGETVPKPGVTPSKSTSASAIMNGGKPVNKSKTT 247
               ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db         196 KPAAHFLPKPLEVAMYREPSLHDVGETVPKPGVTPSKSTSASAIMNGGKPVNKSKTT 252
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As such, the antibodies (claims 15-28 and 43-56) as directed to the contiguous regions of identity inherently bind the claimed protein. Greene et al teach antibodies bound to polystyrene solid phase carriers for immunoassays (column 16, lines 32-33). Greene et al teach labeled antibodies (radioactivity, fluorescent or enzyme (column 16, lines 28-31). Enzymes are broadly ligands for specific proteins.

Applicants should note that prior invention may not be established under 37 CFR 1.131 because this rejection is based upon a U.S. patent or U.S. patent application

publication of a pending or patented application to another or others which claims the same patentable invention as defined in § 41.203(a) of this title, in which case an applicant may suggest an interference pursuant to § 41.202(a) of this title.

Claims 19, 20, 38 and 40-45 are rejected under 35 U.S.C. 102(e) as being anticipated by Hu et al (U.S. Patent 5,817,485, issued October 6, 1998, with priority to March 8, 1994).

Applicant argues that since Hu et al does not teach SEQ ID NO:4 or 11, that the reference does not inherently anticipate the instantly claimed invention because the antibodies of the prior art may bind regions that are different. This is not persuasive because the claims are not limited to regions of difference. This is also not persuasive because Hu et teach antibodies raised against fragments bind the polypeptide (column 11, lines 56-60). Hu et al contemplates monoclonal antibodies, polyclonal antibodies, chimeric antibodies, humanized antibodies, single chain antibodies and Fab fragments and compositions comprising such. The antibodies raised to fragments of the identical contiguous regions of the two proteins would necessarily bind the other protein, not withstanding the regions of difference. Regions of similarity are known to provide for cross-reactivity of an antibody. It was well established in the art at the time the invention was made that antibodies raised to one polypeptide would also specifically bind other polypeptides sharing the epitope recognized by the antibody. For example, Bost et al. (Immunol. Invest. 1988; 17:577-586) teach that an antibody specifically bound an epitope shared by two different polypeptides, but did not bind irrelevant peptides not sharing this epitope. The epitope was determined to be a homologous sequence in the two proteins in which 4 of 6 residues were identical (see entire document, but especially the Abstract, Discussion, and "Results", page 579). Similarly, Bendayan (J. Histochem. Cytochem. 1995; 43:881-886) characterized the specific reactivity of a monoclonal antibody produced to

human proinsulin and showed that although the antibody was highly specific, it bound to not only human proinsulin, but to proinsulin from other species (see entire document). There is no evidence of record that either the polyclonal or monoclonal antibodies of Hu et al does not bind SEQ ID NO:4. Hu et al teaches polyclonal, monoclonal, chimeric, single chain, humanized antibodies and Fab fragments at column 11, line 42 to column 12, line 13. As such, Hu et al anticipates the instantly claimed invention because it teaches antibodies raised to any fragment, and multiple fragments of the polypeptide of Hu et al are 100% identical and define regions of identity between the two polypeptides.

New Rejections Based on Amendment

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 19, 20 and 40-47 are rejected under 35 U.S.C. 103(a) as being unpatentable over Greene et al (US Patent No. 6,482,408, with priority to June 5, 1995) in view of Harlow et al, (Antibodies A Laboratory Manual, 1989, Cold Spring Harbor Laboratory, Chapter 9, pages 319-358) and Nathans et al (5,872,226, with priority to May 12, 1995)

The teachings of Greene et al are set forth supra. Greene et al teach labeling antibodies with enzymes, radioitotopes and fluorochromes. Greene et al differs by not teaching specific detectable labels/ligands.

Harlow et al teach labeling with radioiodine, biotin, horseradish peroxidase, alkaline phosphatase, beta-galactosidase, fluorsescein and rhodamine.

Nathans et al teach anti-FHF antibodies can be bound to different carriers include, glass, polystyrene, polypropylene, polyethylene, dextran, nylon, amylases, natural and modified celluloses, polyacrylamides, agarose and magnetite (column 9, lines 55-64). Nathans et al teach anti-FHF antibodies can be labeled with enzymes, radioisotopes, fluorescent compounds, colloidal metals, chemiluminescent compounds, phosphorescent compounds and bioluminescent compounds and compounds such as biotin, dinitrophenyl, puridoxal and fluorescein.

It would have been *prima facie* obvious to one of ordinary skill in the art at the time that the invention was made to use any available label/ligand and solid phase such as those described by Harlow et al and Nathans et al to label the antibody or immobilize the antibody of Greene et al because Greene et al teach that the antibodies can be labeled and immobilized and such treatment facilitates detection of the antigen or diagnosis of disease.

Status of Claims

Claims 19, 20 and 40-47 stand rejected. Claims 21-37 are withdrawn from consideration.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia A. Duffy whose telephone number is 571-272-0855. The examiner can generally be reached on M-Th 7:30 am - 6:00 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's Supervisor, Shanon Foley can be reached on 571-272-0898.

The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Patricia A. Duffy

Primary Examiner

Art Unit 1645